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DEC 1 2 2012

K122423

Section 5 510(k) SUMMARY

Submitter Information:

Submitter: MEDCOMP®
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Harleysville, PA 19438
Telephone: (215) 256-4201, ext. 2271
Fax: (215) 256-9191
Contact: Jessica Leo
Date Prepared: October 1, 2012

Device Name: Vascu-PICC®
Common Name: Catheter, Intravascular, Therapeutic, Long-Term
Classification Name: Long Term Intravascular Catheter (LJS 78)
C.F.R. Section: 880.5970
Class: II

Predicate Devices: K003682 Z-Cath PICC
K121094 Vascu-PICC and Midline Catheters
K091586 Vascu-PICC and Midline Catheters

Device Description:

The Vascu-PICC taperless catheters are designed for peripheral vein catheterization. The lumen is an open-ended design comprised of a soft radiopaque polyurethane material with barium sulfate for radiopacity. The lumen is connected to the extensions via a soft pliable hub with suture wing for secure placement. Clamps are provided on the extension tubes to prevent air/fluid communication. Female luer connectors provide the connection for intravenous administration.

The catheters are available in a range of French sizes in single, double and triple lumen. The outside diameter of the lumen is the same throughout the length of the catheter, providing patients with superficial vasculature consistent luminal sizing.The lumen has depth marks every centimeter and numerical marks every 5th centimeter and are available in a trim able 60 cm. All extensions have in-line clamps to control fluid flow and the clamps have an I.D. Ring marked with the gauge size and French size.

The Vascu-PICC® catheter product line is packaged sterile with the necessary accessories to facilitate catheter insertion.

Intended Use:

The Vascu-PICC catheters are designed for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling. For central venous pressure monitoring (CVP), it is recommended that catheter lumen of 20 gauge or larger be used.

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Indications for Use:

The Peripherally Inserted Central Vein Access Catheters are designed for long or short- term peripheral access to the central venous system for intravenous therapy and blood sampling and allows for central venous pressure monitoring.

Comparison to Predicate Devices:

The Vascu-PICC® catheters are substantially equivalent to the predicate devices in terms of intended use, anatomical location, basic design, performance, labeling, manufacturing process, method of sterilization and materials.

The difference between the Vascu-PICC® and the predicate Vascu-PICC® device is the taperless lumen design which is based on the original Z-Cath.

Bench / Performance Data:

The following in-vitro testing was performed on the Vascu-PICC® Catheter to assure reliable design and performance in accordance with ISO standards.

Air Leakage
Liquid Leakage
Force at Break
Elongation
Gravity Flow Rate
Infusion Simulation
Priming Volume
Catheter Collapse
Aging
Chemical Testing

Biocompatibility:

All materials used for the Vascu-PICC are identical to the predicate Vascu-PICC (K121094 and K091586) and Z-Cath Picc (K003682) and have been submitted in previously cleared Medcomp submissions. All biocompatibility testing demonstrated the materials used meet the requirements of ISO 10993.

Technological characteristics:

The principles of operation are the same as the predicate devices. The lumen design change does not affect the safety or effectiveness of the device.

Conclusion:

The proposed devices meet the performance criteria of design verification as specified by ISO standards and test protocols. The proposed devices are substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 12, 2012

Ms. Jessica Leo
Regulatory Associate
Medical Components Incorporated
1499 Delp Drive
Harleysville, PA 19438

Re: K122423
Trade/Device Name: Vascu-PICC®
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: November 27, 2012
Received: November 27, 2012

Dear Ms. Leo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122423

Device Name: ___ Vascu-PICC® _____

Indications for Use:

The Peripherally Inserted Central Vein Access Catheters are designed for long or short-term peripheral access to the central venous system for intravenous therapy and blood sampling and allows for central venous pressure monitoring.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Richard C. Chapman
Date: 2012.12.10 12:16:00 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122423